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Quality Specialist

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Company: ProPharma

Location: United Kingdom

Category: other-general

Company profile For the past 20 years, ProPharma has improved the health and wellness of patients by providing advice and expertise that empowers biotech, med device, and pharmaceutical organizations of all sizes to confidently advance scientific breakthroughs and introduce new therapies. As the world’s largest RCO (Research Consulting Organization), ProPharma partners with its clients through an advise-build-operate model across the complete product lifecycle. With deep domain expertise in regulatory sciences, clinical research solutions, quality & compliance, pharmacovigilance, medical information, and R&D technology, ProPharma offers an end-to-end suite of fully customizable consulting solutions that de-risk and accelerate our partners’ most high-profile drug and device programs.The Opportunity The Quality Specialist position supports the delivery of Medical Information and Pharmacovigilance services, to assure ongoing compliance with quality and industry regulatory requirements. The Quality Specialist performs improvement activities through continuous monitoring and evaluation of the quality system to ensure ongoing maintenance. This position may also support regional and global activities as required.ResponsibilitiesRetrospectively evaluates telephone skills and case reports to ensure compliance standards are met and maintained.Generate and prepare reports to communicate outcomes of quality activities.Analyze and investigate, Deviations and Quality Events to identify areas for improvement in the quality system.Review, approve, and communicate root cause and corrective action to stakeholders.Develop, recommend, and monitor corrective and preventive actions. Tracks documentation, as necessary.Collect, management, and analysis of data related to CAPAs, Deviations and quality KPIs.Record,

track, and trend audit findings and response times.Support the Quality Manager during external client audits or regulatory inspections by creating reports, gathering documents, and supplying requested data.Perform effectiveness checks on Deviations and Quality Events to determine efficacy of CAPAs.In conjunction with the Quality Manager, conducts routine Pharmacovigilance audits.Supports and facilitates eQMS activities (i.e., Document Management, QA review and approvals, Change Control assessments, etc.)Other duties as needed.Maintain awareness of and ensure compliance with the Good Pharmacovigilance Practices (GVP), Good Clinical Practices (GCP) requirements, and Good Documentation Practices (GDP).Experience required A Degree and/or or appropriate relevant work experience.2 years' experience working in a Quality Assurance role.Experience of with assessing telephone calls in a call center is preferred.Deviations and CAPA handling experience.Quality or Six Sigma Certifications are an advantage.Work in a professional manner with clients, team members and management.Analytical skills to gather and interpret data. Must be able to identify trends and outliers.Excellent written and verbal communication skills in providing feedback and identifying improvements where needed.Ability to prioritize and organize the tracking of data, documentation maintenance and record keeping.Excellent accuracy and attention to detail to ensure all products and services meet standard requirements.Proactive with the ability to work with minimal supervision.Additional InformationWe celebrate our differences and strive to create a workplace where each person can be their authentic self. We are committed to diversity, equity, and inclusion. Employees are encouraged to unleash their innovative, collaborative, and entrepreneurial spirits. With a holistic approach as an Equal Opportunity Employer, we provide a safe space where all employees feel empowered to succeed.***ProPharma Group does not accept unsolicited resumes from recruiters/third parties. Please, no phone calls or emails***

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